HFA-305

Approval date: APR 1 1999

FREEDOM OF INFORMATION SUMMARY

Supplemental New Animal Drug Application
NADA 040-209

ROFENAID® 40
(sulfadimethoxine and ormetoprim Type A medicated article)

"...for the prevention of coccidiosis caused by *Eimeria kofoidi* and *E. legionensis* in chukar partridges."

Sponsored by:

ROCHE VITAMNS, INC.

NADA 040-209

FOIS 1

I. GENERAL INFORMATION

NADA Number:	040-209
Sponsor:	Roche Vitamins, Inc. 45 Waterview Boulevard Parsippany, New Jersey 07054
Accepted Name:	sulfadimethoxine and ormetoprim Type A medicated article
Trade Name:	ROFENAID® 40
Marketing Status:	This is an over-the-counter (OTC) medicated premix.
Supplemental Effect:	Provides for the use of this sulfadimethoxine and ormetoprim medicated premix for the prevention of coccidiosis (*Eimeria kofoidi* and *E. legionensis*) in chukar partridges. *Minor Species Classification*: Chukar partridges are classified as minor species. Therefore, this supplement addresses minor species requirements with respect to effectiveness and target animal safety data collection.

II. INDICATIONS FOR USE IN CHUKAR PARTRIDGE

ROFENAID® 40 (sulfadimethoxine and ormetoprim) Type A medicated article is indicated for the prevention of coccidiosis caused by *Eimeria kofoidi* and *E. legionensis* in chukar partridges.

III. PRODUCT INFORMATION

A. Dosage Form: ROFENAID® 40 Type A medicated article is available in 50 lb bags. A pound of ROFENAID® 40 is added to one ton of feed to obtain 0.02% (0.0125% sulfadimethoxine and 0.0075% ormetoprim) concentration in feeds.

B. Route of Administration: Orally via feed

C. Recommended Dosage: Feed continuously to young birds up to 8 weeks of age as a sole ration at the rate of 113.5 g/ton (0.0125%) of sulfadimethoxine and 68.1 g/ton (0.0075%) of ormetoprim.

IV. EFFECTIVENESS

Five pivotal studies demonstrating the effectiveness of sulfadimethoxine and ormetoprim premix in chukar partridges were conducted under Public Master File (PMF) 5157. A notice of availability of this data in PMF 5157 was published in the FEDERAL REGISTER of July 19, 1996 (61 FR 37753).

V. ANIMAL SAFETY

A safety study conducted under PMF 5157 with 2.4X the recommended level of sulfadimethoxine and ormetoprim in complete feed for 28 days demonstrated no abnormalities in chukar partridges. A notice of availability of this data in PMF 5157 was published in the FEDERAL REGISTER of July 19, 1996 (61 FR 37753).

Although a study with 5X the recommended level of medicated feed was not conducted in chukars, a finding of no toxicity in chicks (pullets) fed a higher level of medicated feed (4X the recommended level) for 20 weeks was accepted as a basis for not requiring any additional safety studies in chukar partridges This data extrapolation is in accordance with 21 CFR 514.1(d)(2)(i).

VI. HUMAN FOOD SAFETY

The need for a tissue residue depletion study has been waived for the use 0.0125% of sulfadimethoxine and 0.0075% of ormetoprim in chukar partridges due to the extended period between treatment and release into commercial game preserves. The drug will be used to prevent coccidiosis, which is a disease of young birds (up to 8 weeks of age), and the birds will not be released into game preserves until at least 18 weeks of age. Therefore, the need for a tissue residue study is waived (61 FR 37753, July 19, 1996).

Tolerances of 0.1 ppm are established for residues of sulfadimethoxine and ormetoprim in edible tissues of chukar partridges.

VII. AGENCY CONCLUSIONS

The data submitted in support of this supplemental NADA comply with the requirements of Section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR 514.1 of the implementing regulations. The data demonstrate that ROFENAID® 40 Type A medicated article (sulfadimethoxine and ormetoprim medicated feed), when used under labeled conditions of use is safe and effective for the prevention of coccidiosis caused by *Eimeria kofoidi* and *E. legionensis* in chukar partridges.

In accordance with 21 CFR 514.106(b)(2)(vii), this is a Category II supplement. This supplement provides for the use of sulfadimethoxine and ormetoprim medicated feed in chukar partridges, a new animal species. The approval of this change is not expected to have any adverse effect on the safety and effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

The use of the drug in chukar partridges has an inherent withdrawal period since birds are treated at a young age and subsequently held to maturity prior to release into game preserves. Therefore, the Center for Veterinary Medicine has waived the requirements for conducting a tissue residue depletion study. Tolerances of 0.1 ppm are established for residues of sulfadimethoxine and ormetoprim in edible tissues of chukar partridges.

The agency has determined that under 21 CFR 25.33(d)(4) this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Adequate directions for use of the product to treat chukar partridges has been written for the layperson, and the conditions for use prescribed on the labeling are likely to be followed in practice. Therefore, the Center for Veterinary Medicine (CVM) has concluded that this product shall continue to have over-the-counter marketing status.

VIII. APPROVED PRODUCT LABELING

A copy of the draft facsimile labeling is attached to this document.

A. Rofenaid® 40 Type A Medicated Article Bag Label

B. Blue Bird Label for Type C Medicated Feed

12 of 5 BARCODE
LOCATION
FOR POSITION ONLY

ITEM # 04 42364 B12

LOT NO.
EXPIRES

ROFENAID® 40

brand of
sulfadimethoxine & ormetoprim

Type A Medicated Article
(medicated premix)

Antibacterial **Anticoccidiocidal**

FOR USE IN BROILER, REPLACEMENT (BREEDER AND LAYER) CHICKENS, TURKEYS, DUCKS AND CHUKAR PARTRIDGES ONLY

Active Drug Ingredients - sulfadimethoxine 113.5 grams per pound (25%) ormetoprim 68.1 grams per pound (15%) in a carrier suitable for incorporation in feed.

FOR USE IN MANUFACTURING MEDICATED FEEDS ONLY

BROILER AND REPLACEMENT (BREEDER AND LAYER) CHICKENS:
As an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti* and *E. mivati*; as an aid the prevention of bacterial infections caused by *H. gallinarum* (Infectious Coryza), *E. coli* (Colibacillosis) and *P. multocida* (Fowl Cholera).

TURKEYS:
As an aid in the prevention of coccidiosis caused by *E. adenoeides, E. gallopavonis,* and *E. meleagrimitis*; as an aid in the prevention of bacterial infections caused by *P. multocida* (Fowl Cholera).

DUCKS:
As an aid in the control of bacterial infections caused by *E. coli, P. multocida* and *P. anatipestifer.*

CHUKAR PARTRIDGES:
For the prevention of coccidiosis caused by *E. kofoidi* and *E. legionensis.*

IMPORTANT: SEE BACK PANEL FOR WARNINGS AND USE DIRECTIONS.

Roche

Roche Vitamins Inc.
Parsippany, New Jersey 07054

Net Weight 50 Lb. (22.68 kg)

1198 NADA 40-209, APPROVED BY FDA. MADE IN U.S.A.

Roche®

Roche®

ROFENAID® 40
brand of sulfadimethoxine & ormetoprim
Type A Medicated Article (medicated premix)
Antibacterial
Anticoccidiocidal

One Color - Black, Front Panel + Gusset @ 40%

ROFENAID® 40

brand of

sulfadimethoxine & ormetoprim

BROILER & REPLACEMENT CHICKENS

USE DIRECTIONS:
Add 1 Lb. of Rofenaid 40 to one ton of feed to provide 0.02% (0.0125% sulfadimethoxine and 0.0075% ormetoprim) concentration in feed.

INDICATIONS:
As an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti* and *E. mivati*; as an aid in the prevention of bacterial infections caused by *H. gallinarum* (infectious coryza), *E. coli* (colibacillosis) and *P. multocida* (fowl cholera).

LIMITATIONS:
Feed continuously as the sole ration.

WARNING
Do not feed to chickens over 16 weeks (112 days) of age.
WITHDRAW 5 DAYS PRIOR TO SLAUGHTER.

TURKEYS

USE DIRECTIONS:
Add 1/2 Lb. of Rofenaid 40 to one ton of feed to provide 0.01% (0.00625% sulfadimethoxine and 0.00375% ormetoprim) concentration in feed.

INDICATIONS:
As an aid in the prevention of coccidiosis caused by *E. adenoeides, E. gallopavonis*, and *E. meleagrimitis*; for the prevention of bacterial infections caused by *P. multocida* (fowl cholera).

LIMITATIONS:
Feed continuously as the sole ration.

WARNING
Do not feed to turkeys producing eggs for food.
WITHDRAW 5 DAYS PRIOR TO SLAUGHTER.

DUCKS

USE DIRECTIONS:
Add 2 Lb. of Rofenaid 40 to one ton of feed to provide 0.04% (0.025% sulfadimethoxine and 0.015% ormetoprim) concentration in feed.

INDICATIONS:
As an aid in the control of *P. multocida* (fowl cholera) in ducks including breeding ducks.

LIMITATIONS:
Feed for 7 days as the sole ration.
Caution: For control of duck disease, medication should be started at the first signs of infection.
The safety of feeding Rofenaid at levels higher than 0.04% in breeding ducks has not been established.

Add 4 Lb. of Rofenaid 40 to one ton of feed to provide 0.08% (0.050% sulfadimethoxine and 0.030% ormetoprim) concentration in feed.

As an aid in the control of *E. coli, P. anatipestifer* (strains 2,3 & 4) and severe challenge of *P. multocida* (fowl cholera).

WARNING
Do not feed to ducks producing eggs for food.
WITHDRAW 5 DAYS PRIOR TO SLAUGHTER.

CHUKAR PARTRIDGES

USE DIRECTIONS:
Add 1 Lb. of Rofenaid 40 to one ton of feed to provide 0.02% (0.0125% sulfadimethoxine and 0.0075% ormetoprim) concentration in feed.

INDICATIONS:
For the prevention of coccidiosis caused by *Eimeria kofoidi* and *E. legionensis*.

LIMITATIONS:
Feed continuously as the sole ration to young birds up to 8 weeks of age.
The safety of feeding Rofenaid to breeding stock has not been established.

NOTE: Manufacture of Type B or C feeds from this product requires a Medicated Feed License Application approved by FDA.

Labels for feeds containing Rofenaid 40 must contain appropriate indications, limitations and warnings as well as required feed ingredient information.

TAKE TIME

OBSERVE LABEL DIRECTIONS

One color black
40%
Black on white

Net Weight Shown on Bag;
on Invoice if Bulk.

May be Used as Placard
for Bulk Feeds

BLUE BIRD LABEL

BAG OR BULK

____ Lbs (kgs) Net Weight, If Bag

CHUKAR PARTRIDGES
(TYPE C FEED)
MEDICATED

For the prevention of coccidiosis caused by Eimeria kofoidi and E. legionensis in Chukar partridges.

ACTIVE DRUG INGREDIENTS

Sulfadimethoxine	113.5 g/ton (0.0125%)
Ormetoprim	68.1 g/ton (0.0075%)

GUARANTEED ANALYSIS

Crude Protein	Min%
Lysine	Min %
Methionine	Min %
Crude Fat	Min %
Crude Fiber	Max %
Calcium	Min %
Calcium	Max %
Phosphorus	Min %
Salt	Min %
Salt	Max %

INGREDIENTS

Each ingredient must be listed as defined by AAFCO.

USE DIRECTIONS

Feed continuously as the sole ration to young birds up to 8 weeks of age.
The safety of feeding Rofenaid to breeding stock has not been established.

MANUFACTURED BY

Blue Bird, Inc.
Anywhere, USA 00000

GU3-99